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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,974	PICKUP ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-100,102-109,118-128,131-133,136,140,148-150 and 183-185* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-100,102-109,118-128,131-133,136,140,140,148-150,183-185* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 15, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding amended claim 83 and new claims 183 and 184: Applicant argues that Svedman does not teach that the instant bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface. This is not persuasive because throughout the disclosure, Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open space, or air, between the orifice where the droplets of composition exit and the subcutaneous surface defining the base of the de-epithelialized delivery site. The droplets enter this open space upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site. Similarly, with respect to amended claim 91 and new claims 183, the orifice is spaced from and is directly above a face of the patch

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 83-85, 87-89, 91-95, 98, 99, 102,105-107, 118, 123, 126, 131, 136, 140, 141 and 183-185 are rejected under 35 U.S.C. 102(b) as being anticipated by Svedman (U.S. Patent No. 6,048,337)

With respect to **claim 83:** Svedman teaches a method of administering a bioactive composition to a subject, the method comprising: applying to a cutaneous surface of the subject a jet dispenser comprising a container in the form of drug cell 174/175 holding the bioactive composition (Fig. 78, Col. 35, lines 46-48). The method also comprises the step of dispensing the bioactive composition in droplets from the dispenser through at least one orifice in the form of an array of nozzles toward the cutaneous surface such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface. (Col. 35, lines 51-63) Examiner's position is based upon Svedman's teaching regarding the technique for creating a delivery site on the cutaneous surface prior to dispensing the composition. Specifically, throughout the disclosure Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open space, or air, between the orifice where the droplets of composition exit and the cutaneous surface containing the de-epithelialized delivery site. The droplets enter this open air space or gap upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the

delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site. With regard to the limitation "retaining the bioactive composition in prolonged contact with the cutaneous surface", applicant discloses no quantitative time interval range for "prolonged contact with the cutaneous surface" and only discloses that this prolonged contact is accomplished by attaching the claimed device to the cutaneous surface. Since Svedman teaches that the dispenser is attached to the cutaneous surface of a user via suction, this limitation flows inherently and necessarily from the teachings of Svedman. (Abstract)

With respect to **claim 84:** Svedman teaches an embodiment in Fig. 70 in which the step of retaining the bioactive composition in prolonged contact with the cutaneous surface comprises dispensing the bioactive composition on to a patch 121 that is retained on the cutaneous surface. (Col. 31, lines 16-21)

With respect to **claim 85:** The patch 121 is an adhesive dermal patch having adhesive layer 125 that is applied to the cutaneous surface prior to dispensing the bioactive composition from the dispenser. (Col. 32, lines 56-61)

With respect to **claim 87:** Svedman teaches a method wherein retaining the bioactive composition in prolonged contact with the cutaneous surface comprises providing a seal between the dispenser and cutaneous surface via application of suction to form a substantially sealed chamber between the dispenser and the cutaneous surface, and retaining the dispenser in prolonged contact with the seal. (Abstract)

With respect to **claim 88:** Svedman teaches repeatedly dispensing the bioactive composition toward the cutaneous surface inasmuch as Svedman teaches that the patch 121 is in registration with the cutaneous surface for several days and teaches that the patch remains in place “for a subsequent procedure”, interpreted herein as a subsequent dispensation of said drug. (Col. 32, lines 62-66)

With respect to **claim 89:** Svedman teaches the step of filling a drug reservoir with liquid drug and a drug insertion port 685 in association with the embodiment of Fig.29, upon which the embodiment of Figs 63-69 is based. Thus Svedman teaches the step of resupplying the dispenser with the bioactive substance. (Col. 21, lines 27-33, Col. 22, lines 12-17)

With respect to **claim 91:** Svedman teaches a method of administering a bioactive composition to a subject, the method comprising: applying a cutaneous patch 121 to the skin of the subject (Fig. 63, Col. 31, lines 13-16); and dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of site 8 (the site to which patch 121 is ultimately delivered) or the patch 121 in the form of aperture 6. (Figs. 63,65,66, Col. 31, lines 12-15)

With respect to **claim 92:** Svedman is considered herein to teach dispensing the bioactive composition to the patch at intervals inasmuch as Svedman teaches that the patch 121 is in registration with the cutaneous surface for several days and teaches that the patch remains in place “for a subsequent procedure”, interpreted herein as a subsequent dispensation of said drug. (Col. 32, lines 62-66) The limitation “to provide sustained dosages of the bioactive

composition from the patch to the subject" constitutes functional language that is given little patentable weight herein.

With respect to **claim 93:** The intervals are preselected intervals inasmuch as the delivery of drug dosages is controlled. (Col. 8, lines 21-34)

With respect to **claim 94:** The method taught by Svedman further comprises controlling the rate of drug delivery to stabilize a measured parameter at a desired level, i.e. dispensing the bioactive composition from the dispenser to the patch 121 when an amount of the bioactive composition in the patch rises above or falls below a desired level as detected by biosensor 168. (Col. 36, lines 1-8)

With respect to **claim 95:** Svedman teaches an embodiment in Fig. 53 wherein the step of dispensing further comprises dispensing a second substance from a second compartment 71 from the dispenser to the patch 121 (Col. 28, lines 15-27). Svedman teaches an embodiment in Fig. 80 wherein drug cell 145 contains a drug mixed with a hydrogel prior to dispensing.

With respect to **claim 98:** The method taught by Svedman further comprises containing said bioactive composition with a container portion, e.g. collection chamber 160 of said inkjet dispenser prior to said dispensing. (Fig. 78, Col. 35, lines 27-29)

With respect to **claim 99:** The method taught by Svedman further comprises filling said container portion 160 prior to any dispensation of drug, thus since Svedman teaches repeated

administrations of said drug, Svedman also teaches refilling said container portion with said bioactive composition. (Fig. 78, Col. 35, lines 27-29)

With respect to **claim 102:** The dispensing step taught by Svedman comprises using a thermal droplet jet dispenser. (Col. 34, lines 54-64)

With respect to **claim 105:** The inkjet dispenser used in said dispensing comprises a thermal inkjet dispenser, wherein dispensing the bioactive composition from the thermal inkjet dispenser comprises receiving the bioactive composition into a feed chamber 160 from a reservoir 145 in the dispenser (Col. 35, lines 25-32). The method further comprises the step of flowing the bioactive composition from the feed chamber 160 into a vaporization chamber within pump 177 in the dispenser (Col. 35, lines 54-58). The limitations “energizing a firing resistor in the vaporization chamber”and “ejecting the bioactive composition as a droplet from the vaporization chamber” flow inherently and necessarily from Svedman’s teachings of a thermal jet droplet dispenser having electrical heating element 179 (Col. 35, lines 58-63, Col. 36, lines 11-15).

With respect to **claim 106:** The method of the combined teaching of Svedman and Hayes teaches a piezoelectric inkjet dispenser, The limitations “dispensing the bioactive composition from the piezoelectric inkjet dispenser comprises receiving the bioactive composition into a piezoelectric chamber from a storage chamber in the dispenser”,” passing an electric current through a piezoelectric member in the chamber, thereby expanding the piezoelectric member” and “expelling the bioactive composition as a droplet from the vaporization chamber” flow inherently and necessarily from the device fairly suggested by Svedman as supported by Hayes, which fairly suggests a piezoelectric inkjet dispenser.

With respect to **claim 107:** The method of the combined teaching of Svedman and Hayes teaches a step of dispensing comprises a silicon electrostatic actuated inkjet dispenser as stated *supra* with respect to claim 104.

With respect to **claim 118:** Svedman teaches monitoring a physical parameter of the subject via monitoring of the value of the parameter in a sample of exudates from exposed dermis at the injection site on the user (Col 36, lines 1-6); and in response to said monitoring, controlling the rate of drug delivery to stabilize the measured parameter at a desired level, i.e. adjusting said dispensing. (Col 36, lines 1-6)

With respect to **claim 123:** The monitoring comprises using a monitor portion in the form of biosensor 168 of the jet dispenser. (Col. 35, lines 34-42)

With respect to **claim 126:** Svedman teaches monitoring a physical parameter of the subject via monitoring of the value of the parameter in a sample of exudates from exposed dermis at the injection site on the user (Col 36, lines 1-6); and in response to said monitoring, controlling the rate of drug delivery to stabilize the measured parameter at a desired level, i.e. adjusting said dispensing. (Col 36, lines 1-6)

With respect to **claim 131:** The monitoring comprises using a monitor portion in the form of biosensor 168 of the jet dispenser. (Col. 35, lines 34-42)

With respect to **claim 136:** Svedman teaches applying a bioactive composition attracting agent in the form of patch 121 to a treatment location on the cutaneous surface of the subject in the form of an iontophoresis process; pulling the bioactive composition toward said agent by applying a voltage of appropriate polarity between a first electrode 187 within cell 145 where the drug is located, and second electrode 188 located adjacent the skin peripheral to the de-epthelialized site (i.e. the injection site). The difference in voltage has an associated mechanical force that drives the drug from cell 145 toward the injection site for absorption. The drug then penetrates said agent 121 with the bioactive composition to treat the treatment location with the bioactive composition. (Col. 36, lines 53-62)

With respect to **claim 140:** Svedman teaches manually triggering an activation device 127 after said applying and before said dispensing via patch 121, with said dispensing occurring in response to said triggering, specifically actuator 127 displaces support ring and with it patch 121 in a direction that is at a right angle to base 3, which is depicted in Fig. 63 as the outermost housing surrounding the entire dispenser. (Col. 31, lines 44-48, Col. 32, lines 51-56)

With respect to **claim 141:** Svedman teaches manually triggering an activation device 127 after said applying and before said dispensing via patch 121, with said dispensing occurring in response to said triggering, specifically actuator 127 displaces support ring and with it patch 121 in a direction that is at a right angle to base 3, which is depicted in Fig. 63 as the outermost housing surrounding the entire dispenser. (Col. 31, lines 44-48, Col. 32, lines 51-56)

With respect to **claim 183:** The step of dispensing taught by Svedman is performed with the orifice spaced from and directly above a face of site 8 (the site to which patch 121 is ultimately delivered) or the patch 121 in the form of aperture 6. (Figs. 63,65,66, Col. 31, lines 12-15)

With respect to **claim 184:** The dispensing step of the method of Svedman is performed such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface. (Col. 35, lines 51-63) Examiner's position is based upon Svedman's teaching regarding the technique for creating a delivery site on the cutaneous surface prior to dispensing the composition. Specifically, throughout the disclosure Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open space, or air, between the orifice where the droplets of composition exit and the cutaneous surface containing the de-epithelialized delivery site. The droplets enter this open air space or gap upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site.

With respect to **claim 185:** The method also includes the step of dispensing the bioactive composition as droplets from the dispenser that travel from the at least one orifice in the form of an array of nozzles toward the cutaneous surface 8 (or ultimately, patch 121) across an airgap that extends directly from the orifice to the patch 121. (Col. 35, lines 51-63) Examiner's position

is based upon Svedman's teaching regarding the technique for creating a delivery site on the cutaneous surface prior to dispensing the composition. Specifically, throughout the disclosure Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open space, or air, between the orifice where the droplets of composition exit and the cutaneous surface containing the de-epithelialized delivery site. The droplets enter this open air space or gap upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 86, 96, 97,119, 120, 127, 128 and 148-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337).

With respect to **claim 86:** The patch 121 comprises a selectively removable cover in the form of conventional patch 135. (Col. 32, lines 51-61) The removable cover 135 is subsequently replaced on the patch. The limitation "to improve retention of the bioactive composition in the patch" constitutes functional language that is given little patentable weight herein.

Svedman does not explicitly teach that cover 121 is removed prior to dispensing the bioactive composition into the patch. However, Svedman teaches that patch 121 can be used alone or with cover 135 to deliver said drug. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the cover 135 is removed prior to dispensing the bioactive composition into patch 121 with a reasonable expectation of success, as the patch 121 can still perform the intended function of delivering the drug without the cover 135 present.

With respect to **claim 96:** Svedman does not teach a method wherein said mixing occurs between said orifice and said patch. However, Svedman teaches collection chamber 160 wherein liquid samples can be collected and drug is channeled from the reservoir(s) e.g. cell 145 or compartments 71, thus it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the drugs in said compartments 71 are mixed between the orifice and the patch 121 with a reasonable expectation of success as there are only a finite number of points at which the drugs can be mixed. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

With respect to **claim 97:** Svedman does not teach a method wherein said mixing occurs within said patch. However, Svedman teaches collection chamber 160 wherein liquid samples can be collected and drug is channeled from the reservoir(s) e.g. cell 145 or compartments 71, thus it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the drugs in said compartments 71 are mixed between the orifice and the patch 121 with a reasonable expectation of success as there are only a finite number of points at which the drugs can be mixed. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

With respect to **claim 119:** Svedman does not teach that the physical parameter comprises heartbeats. However, since Svedman teaches that the drug comprises pain medication, which slows a human heart rate and teaches controlling drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 120:** Svedman does not teach that the physical parameter comprises breathing. Examiner is interpreting the term "breathing" as equivalent to breathing rate, as it is believed that this is what is intended and is what is disclosed. However, since Svedman teaches that the drug comprises pain medication, which slows breathing rate and teaches controlling drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 127:** Svedman does not teach that the physical parameter comprises heartbeats. However, since Svedman teaches that the drug comprises pain medication, which slows a human heart rate and teaches controlling drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 128:** Svedman does not teach that the physical parameter comprises breathing. Examiner is interpreting the term "breathing" as equivalent to breathing rate, as it is

believed that this is what is intended and is what is disclosed. However, since Svedman teaches that the drug comprises pain medication, which slows breathing rate and teaches controlling drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 148:** Svedman does not teach storing the bioactive composition in a collapsible bladder. However a pouch is simply another container and accomplishes the identical result of confining a drug dosage until use to the drug cell 145, therefore it would be obvious with a reasonable expectation of success to modify the method of Svedman such that the drug is stored in a collapsible bladder to accomplish the result of holding the bioactive composition in a sterile environment prior to use. The method fairly suggested by Svedman teaches conveying the bioactive composition from a container (drug cell 145) to the jet dispenser.

With respect to **claim 149:** In the embodiment taught by Svedman in Fig. 90, said step of conveying from a container 262 comprises conveying the bioactive composition through suction tubing 15. (Col. 38, lines 5-8)

With respect to **claim 150:** Svedman does not teach storing the bioactive composition in a collapsible bladder. However a pouch is simply another container and accomplishes the identical result of confining a drug dosage until use to the drug cell 145, therefore it would be obvious with a reasonable expectation of success to modify the method of Svedman such that the drug is stored in a collapsible bladder to accomplish the result of holding the bioactive

composition in a sterile environment prior to use. The method fairly suggested by Svedman teaches conveying the bioactive composition from a container (drug cell 145) to the jet dispenser.

6. Claims 90 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Rogers (U.S. Patent No. 5,480,062).

With respect to **claim 90:** Svedman teaches that resupplying the dispenser comprises injecting the drug from a separate container and thus does not teach replacing a container in the dispenser. Rogers teaches a vacuum operated medicine dispensing device wherein a plurality of storage containers 210 are sized to receive refill cartridges 212 of medication. Rogers teaches that this allows for the provision of a backup supply of medication, therefore it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that resupplying the dispenser comprises replacing a container in the reservoir (e.g. reservoir 660 in Figs. 28,29) of said dispenser as taught by Rogers to provide a backup supply of drug to ensure timely administration of said drug. ('062, Fig. 2, Col. 7, lines 24-33)

With respect to **claim 100:** A method according to claim 99 further comprising

Svedman does not teach that container 160 is removed and thus does not teach the step of removing said container portion from the inkjet dispenser prior to said refilling, and after said refilling, replacing said container portion for further dispensing. Rogers teaches a vacuum operated medicine dispensing device wherein a plurality of storage containers 210 are sized to receive refill cartridges 212 of medication. Rogers teaches that this allows for the provision of a backup supply of medication, therefore it would be obvious to one of ordinary skill in the art to

modify the device of Svedman such that resupplying the dispenser comprises replacing a container in the reservoir (e.g. collection chamber 160 in Figs. 28,29) of said dispenser as taught by Rogers to provide a backup supply of drug to ensure timely administration of said drug. ('062, Fig. 2, Col. 7, lines 24-33)

7. Claims 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Hayes et al (U.S. Patent No. 6,325,475)

With respect to **claim 103:** Svedman teaches a thermal droplet jet dispenser, but does not teach that the step of dispensing comprises using a piezoelectric droplet jet dispenser. Hayes teaches a jet dispenser for administering airborne materials into a user's nose that utilizes ink-jet technology. Hayes teaches that the transducer in the ink jet device can be piezoelectric or electromechanical (as is taught by Svedman in Col. 35, lines 58-63 and Col. 36, lines 10-15). ('475, Col. 7, lines 29-37) Since Hayes teaches that piezoelectric and electromechanical droplet jet dispensers such as thermal droplet jet dispensers are equivalent methods of creating and dispensing droplets of a drug, it would be obvious to one of ordinary skill in the art to utilize any of piezoelectric, thermal or silicon electrostatic transducers as taught by Hayes. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

With respect to **claim 104:** Svedman teaches a thermal droplet jet dispenser, but does not teach that the step of dispensing comprises using a silicon electrostatic actuated droplet jet dispenser. Hayes teaches a jet dispenser for administering airborne materials into a user's nose

that utilizes ink-jet technology. Hayes teaches that the transducer in the ink jet device can be piezoelectric or electromechanical (as is taught by Svedman in Col. 35, lines 58-63 and Col. 36, lines 10-15). ('475, Col. 7, lines 29-37) Silicon electrostatic actuated droplet dispensers are interpreted herein as an example of an electromechanical dispenser, given their nature of operation as disclosed by applicant:

"The ink ejection mechanism 316 includes a silicon substrate 322 that contains for each nozzle 320 an individually energizable thin film firing resistor 324, each located generally behind an associated single nozzle 320. The firing resistors 324 act as ohmic heaters (electric heaters) when selectively energized by one or more enabling signals or firing pulses 325, which are delivered from a controller 326 through conductors (omitted for clarity) carried by the polymer tape 318." (Specification, [72])

The electric ohmic heaters then heat the drug passing through nozzles 320, which is the mechanical aspect of the silicon-actuated dispenser. Since Hayes teaches that piezoelectric and electromechanical droplet jet dispensers are equivalent methods of creating and dispensing droplets of a drug, it would be obvious to one of ordinary skill in the art to utilize any of piezoelectric, thermal or silicon electrostatic transducers as taught by Hayes. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

8. Claims 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Jacobsen (U.S. Patent No. 5,860,957).

With respect to **claims 108,109:** Svedman does not teach any of the limitations of claim 108 or 109. Jacobsen teaches that a drug is specifically selected by name via the ability of device 20 to

read a label on a drug storage container as it is inserted. An external host interface 48 obtains and stores data via a wireless infrared reading device from a computer having microprocessor 40, said data including user ID, drug ID, dose and usage information. Wireless interface 48 then uses said data to monitor a patient's physiological status in tandem with sensors, this circuit also thus being capable of responding to the data by administering the appropriate dosage via device 20 according to the stored schedule data. (Col. 7, lines 24-38) Since Svedman also teaches monitoring a physical parameter in the instant method, it would be obvious to one of ordinary skill in the art to modify the method of Svedman to include the steps set forth in claim 108 and claim 109 as taught by Jacobsen with a reasonable expectation of success to maintain the parameter value at the desired level.

9. Claims 124, 125, 132 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Meyerson et al (U.S. Patent No. 5,179,947).

With respect to **claim 124:** Svedman teaches that the monitor portion 168 comprises a sensor that is appropriate for the parameter, but does not explicitly teach that the monitor portion comprises a mechanical sensor. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the monitor portion taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

With respect to **claim 125:** Svedman does not teach a mechanical sensor or that said sensor comprises an accelerometer. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the sensor of the device taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

With respect to **claim 132:** Svedman teaches that the monitor portion 168 comprises a sensor that is appropriate for the parameter, but does not explicitly teach that the monitor portion comprises a mechanical sensor. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the monitor portion taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

With respect to **claim 133:** Svedman does not teach a mechanical sensor or that said sensor comprises an accelerometer. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user.

Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the sensor of the device taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761